

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
 United States Patent and Trademark  
 Office  
 Box PCT  
 Washington, D.C.20231  
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 17 October 2000 (17.10.00)	
<b>International application No.</b> PCT/US00/04228	<b>Applicant's or agent's file reference</b> 032905-002
<b>International filing date</b> (day/month/year) 18 February 2000 (18.02.00)	<b>Priority date</b> (day/month/year) 19 February 1999 (19.02.99)
<b>Applicant</b> HAZEN, Kevin, C. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 15 September 2000 (15.09.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer F. Baechler Telephone No.: (41-22) 338.83.38
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## PATENT COOPERATION TREATY

## PCT

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 02 OCT 2001

WIPO

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Applicant's or agent's file reference 032905-002	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/04228	International filing date (day/month/year) 18 FEBRUARY 2000	Priority date (day/month/year) 19 FEBRUARY 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00 and US Cl.: 530/300, 329		
Applicant UNIVERSITY OF VIRGINIA PATENT FOUNDATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

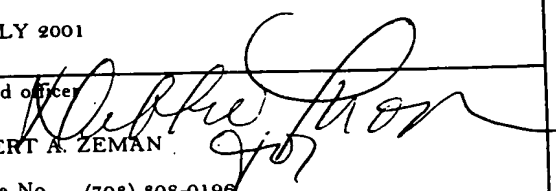
2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  15 SEPTEMBER 2000	Date of completion of this report  03 JULY 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  ROBERT A. ZEMAN
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)\*

**I. Basis of the report****1. With regard to the elements of the international application:\***☒ the international application as originally filed☒ the description:pages 1-41

, as originally filed

pages NONE

, filed with the demand

pages NONE

, filed with the letter of \_\_\_\_\_

☒ the claims:pages 42-50

, as originally filed

pages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the drawings:pages 1-6

, as originally filed

pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_☒ the sequence listing part of the description:pages NONE

, as originally filed

pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 8-48

because:

☐ the said international application, or the said claim Nos. \_ relate to the following subject matter which does not require international preliminary examination (*specify*).

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 25-30, 32-36 are so unclear that no meaningful opinion could be formed (*specify*).

Claims are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. \_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8-24, 31, 37-48.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/04228

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. statement

Novelty (N)

Claims	<u>1-7</u>	YES
Claims	<u>NONE</u>	NO

Inventive Step (IS)

Claims	<u>NONE</u>	YES
Claims	<u>1-7</u>	NO

Industrial Applicability (IA)

Claims	<u>1-7</u>	YES
Claims	<u>NONE</u>	NO

### 2. citations and explanations (Rule 70.7)

Claims 1-7 lack an inventive step under PCT Article 33(s) as being obvious over Proefstation Voor De Champignoncultuur (WO 96/41882 A1). Said reference discloses sequences for hydrophobins and fragments thereof as well as methods of derivation for said proteins. Reference discloses the use of fungi as the source of said protein, but not the specific species used in the instant application. Use of a particular species however, does not constitute an inventive step since it would have been obvious to one of skill in the art to use only species that produce the protein of interest. Consequently, the use of the disclosed methods would yield peptides containing the claimed peptides.

Claims 1-7 lack an inventive step under PCT Article 33(s) as being obvious over Penas et al. (Applied and Environmental Microbiology, October 1998, Vol 64, No. 10, pages 4028-4034). Said reference discloses sequences for hydrophobins and fragments thereof as well as methods of derivation for said proteins. Reference discloses the use of fungi as the source of said protein, but not the specific species used in the instant application. Use of a particular species however, does not constitute an inventive step since it would have been obvious to one of skill in the art to use only species that produce the protein of interest. Consequently, the use of the disclosed methods would yield peptides containing the claimed peptides.

Claims 1-7 lack an inventive step under PCT Article 33(s) as being obvious over Asgeirsdottir et al. (Microbiology, November 1998, Vol. 144, Part II, pages 2961-2969). Said reference discloses sequences for hydrophobins and fragments thereof as well as methods of derivation for said proteins. Reference discloses the use of fungi as the source of said protein, but not the specific species used in the instant application. Use of a particular species however, does not constitute an inventive step since it would have been obvious to one of skill in the art to use only species that produce the protein of interest. Consequently, the use of the disclosed methods would yield peptides containing the claimed peptides.

(Continued on Supplemental Sheet.)

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

----- NEW CITATIONS -----

NONE

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakistan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## INTERNATIONAL SEARCH REPORT

 International application No.  
PCT/US00/04228

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 38/00

US CL : 530/300, 329

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 530/300, 329

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST, STN, MEDLINE

hyrdophobin, yeast, mold, cell wall protein, sequence,

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	SEGRS, G.C. et al. Isolation and characterisation of five different hydrophobin-encoding cDNAs from the funal tomato pathogen <i>Cladosporium fulvum</i> . Molecular and General Genetics. June 1999, Vol. 261, Nos. 4-5, pages 644-652, see whole document.	1-7
Y,P	DE VRIES, O. M. et al. Identification and characterization of a tri-parite hydrophobin from <i>Claviceps fusiformis</i> . A novel type of class II hydrophobin. European Journal of Biochemistry. June 1999, Vol. 262, No. 2, pages 377-385, see whole document.	1-7

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

20 APRIL 2000


Date of mailing of the international search report

27 JUN 2000

 Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

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Authorized officer

  
ROBERT A. ZEMAN

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/04228

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category'	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	PENAS, M. M. et al. Identification, characterization, and In situ detection of a fruit-body-specific hydrophobin of <i>Pleurotus ostreatus</i> . <i>Applied and Environmental Microbiology</i> . October 1998, Vol. 64, No. 10, pages 4028-4034, see entire document.	1-7
Y	ASGEIRSDOTTIR, S. A. et al. Identification of three differentially expressed hydrophobins in <i>Pluerotus</i> . <i>Microbiology</i> . November 1998, Vol. 144(Pt II), pages 2961-2969, see whole document.	1-7
Y	WO 96/41882 A1 (PROEFSTATOPM VOOR DE CHAM PIGNONCULTUUR) 27 December 1996 (27/12/96), see whole document.	1-7

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/04228

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 25-30, 32-36  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/04228

### BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

- Group I, claim(s) 1-7, drawn to peptide I with the structure G-X<sub>1</sub>-X<sub>2</sub>-R.
- Group II, claim(s) 8-12 and 13, drawn to antibody to peptide I and hybridoma that produces said antibody.
- Group III, claim(s) 14 and 19-23, drawn to methods of treating yeast infections using antibodies to peptide I.
- Group IV, claim(s) 15-17, drawn to methods of detecting hydrophobic binding domains using antibodies to peptide I.
- Group V, claim(s) 18, drawn to method of isolating hydrophobic binding domain using antibodies to peptide I.
- Group VI, claim(s) 24, drawn to peptide II with the structure E-X<sub>1</sub>-L-X<sub>2</sub>-X<sub>3</sub>-X<sub>4</sub>.
- Group VII, claim(s) 31, drawn to a hybridoma that produces an antibody to peptide II.
- Group VIII, claim(s) 37-40, drawn to methods of treating yeast infections using peptide II.
- Group IX, claim(s) 41-43, drawn to antibody to peptide III and the hybridoma that produces said antibody.
- Group X, claim(s) 44, drawn to method of treating yeast infection using antibody to peptide III.
- Group XI, claim(s) 45-47, drawn to method of detecting hydrophobic binding domains using antibodies to peptide III.
- Group XII, claim(s) 48, drawn to method of isolating hydrophobic binding domain using antibody to peptide III.

The inventions listed as Groups I-XII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first-recited product, polypeptides. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.